Dupilumab reduces OCS use and improves lung function in patients with severe OCS-dependent asthma

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Background Dupilumab (DPL), a fully human anti-IL-4Rα mAb, blocks interleukin-4/13, key and central drivers of type 2 inflammation. TRAVERSE (NCT02134028), a single-arm, open-label extension study, evaluated the long-term safety and efficacy of DPL 300mg q2w for up to 96 weeks in patients (pts) from VENTURE.

Aim To assess DPL efficacy in TRAVERSE pts with severe OCS-dependent asthma by OCS dose at parent study baseline (PSBL; VENTURE).

Methods Pts from TRAVERSE were analyzed as DPL/DPL or placebo (PBO)/DPL group and stratified by OCS dose (≤10/>10mg/day at PSBL). % reduction in OCS dose and change in pre-BD FEV_1 from PSBL at TRAVERSE Weeks (Wks) 0/96; % of pts achieving 0, <5, or <10mg/day OCS; AER during VENTURE and TRAVERSE were assessed.

Results 187 pts from TRAVERSE were analyzed. The daily-dose % reductions observed in VENTURE continued during TRAVERSE in DPL/DPL pts (Wk96: ≤10mg/day: −89%, >10mg/day: −83%) and PBO/DPL pts (Wk96: ≤10mg/day: −70%, >10mg/day: −76%). The % pts achieving 0, <5, or <10mg/day OCS continued to improve throughout TRAVERSE regardless of OCS dose at PSBL. Also, AER was lower in TRAVERSE (range: 0.284–0.599) vs VENTURE (0.463–1.587), and pre-BD FEV_1 continued to improve in all subgroups (**Table**).

Conclusion OCS dose reductions were sustained, and improvements in AER and lung function continued during TRAVERSE.

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Table. OCS use, AER, and pre-BD FEV_1 at various time points in VENTURE and TRAVERSE.

	VENTURE baseline OCS dose ≤10 mg/day		VENTURE baseline OCS dose >10 mg/day	
	PBO/DPL n=61	DPL/DPL n=60	PBO/DPL n=36	DPL/DPL n=30
OCS use (mg/day)				
VENTURE				
Baseline, mean (SD)	8.07 (2.06)	7.42 (2.16)	17.57 (5.69)	18.08 (5.40)
TRAVERSE				
Week 0, mean (SD)	4.80 (4.50)	1.60 (2.85)	9.10 (9.18)	6.17 (7.95)
Week 96, mean (SD)	2.75 (2.91)	0.63 (1.44)	3.63 (3.50)	4.17 (7.22)
OCS use (reduction from VENTURE PSBL), %				
TRAVERSE				
Week 0, mean (SD)	−42 (52.7)	−79 (36.6)	−52 (42.1)	−65 (44.8)
Week 96, mean (SD)	− 70 (31.7)	− 89 (27.3)	− 76 (23.9)	− 83 (28.9)
Achieved OCS dose (proportion of patients)				
End of VENTURE/start of TRAVERSE				
0 mg/day, n/N (%)	20/61 (33)	40/60 (67)	9/36 (25)	8/30 (27)
<5 mg/day, n/N (%)	25/61 (41)	51/60 (85)	12/36 (33)	16/30 (53)
<10 mg/day, n/N (%)	48/61 (79)	56/60 (93)	22/36 (61)	22/30 (73)
TRAVERSE Week 96				
0 mg/day, n/N (%)	9/20 (45)	13/16 (81)	3/8 (38)	2/3 (67)
<5 mg/day, n/N (%)	11/20 (55)	15/16 (94)	4/8 (50)	2/3 (67)
<10 mg/day, n/N (%)	19/20 (95)	16/16 (100)	7/8 (88)	2/3 (67)
Unadjusted AER				
VENTURE	1.587	0.463	1.492	1.070
TRAVERSE	0.311	0.294	0.284	0.599
Pre-BD FEV_1 (L)				
VENTURE				
Baseline, mean (SD)	1.62 (0.66)	1.50 (0.48)	1.63 (0.57)	1.58 (0.55)
TRAVERSE				
Week 0, mean (SD)	1.63 (0.68)	1.82 (0.60)	1.59 (0.62)	1.82 (0.63)
Week 96, mean (SD)	1.95 (0.97)	1.71 (0.54)	2.11 (0.80)	2.02 (0.70)

All data shown in mean (SD) unless stated otherwise. AER, annualized rate of exacerbations; BD, bronchodilator; DPL, dupilumab; OCS, oral corticosteroid; PBO, placebo; SD, standard deviation.